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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,717	02/19/2002	Kenj Asano	0203-0162P	3321

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,717

Applicant(s)

ASANO ET AL.

Examiner

Christopher R. Tate

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-32 and 34-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-32 and 34-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' election with traverse of Group I in the reply filed on 21 December 2005 is acknowledged. The traversal is on the ground(s) that the same method steps of administering the claimed extract (whereby the extract is prepared in the same manner in each case - i.e., recited as methods of using a product-by-process) and, further, that several Office actions and a Notice of Allowability have been issued in the instant application without any earlier restriction requirement - thus restriction of the claims at this stage is considered an inconsistent position to that taken over the past 4 years and amounts to piecemeal examination. Applicants' arguments are found persuasive. Accordingly, all of the claims set forth in the amendment filed 28 July 2005 are deemed to reasonably read upon a singular invention and, thus, the claims have been rejoined. Claims 24-32 and 34-38 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 24, 25, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagaoka (US 6,090,615) and Nagaoka (US 2004/0038330 - which has an effective filing date of June 9, 1994).

The US '615 reference teaches a *Lentinus edodes* (also known as shiitake mushroom) mycelium (hyphae) extract which is prepared via the same (or essentially the same) steps as instantly claimed, as well as pharmaceutical, drink, oral (food) formulations thereof, and a method of treating tumors therewith (see, e.g., col 1, lines 30-44; col 2, lines 25-63; col 3, lines 6-68; and Example 1, Comparative Examples 1 and 2, Example 4, Comparative Examples 3-4).

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In addition, the US '330 reference teaches a *Lentinus edodes* mycelium extract, prepared via the same (or essentially the same) steps as instantly claimed, which is useful against liver cancer (see, e.g., claim 5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a therapeutic anti-tumor/anti-cancer *Lentinus edodes* (shiitake) mycelium extract via the instantly claimed steps, including formulating such therapeutic extracts into conventional pharmaceutical, drink, and/or oral (e.g., food) preparations, as well as to treat liver cancer (which is typically a tumorous-type cancer) and/or other tumors therewith, based upon the beneficial teachings provided by the cited Nagaoka references with respect to such anti-tumor/anti-cancer activity. Please note, if not expressly taught, the other claim limitations (e.g., that the extract has a particular functional cell activity and/or that it comprises approximate ranges of various ingredients therein) would be intrinsic to the *Lentinus edodes* mycelium extracts taught by US '615 and US '330. The result-effective adjustment in conventional working conditions/parameters (e.g., providing such an extract within one or more conventional pharmaceutical formulations such as those instantly claimed) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited references as a guide.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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Claims 26, 27, 30-32, 34 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagaoka (US 2004/0038330).

The cited reference teaches a *Lentinus edodes* (also known as shiitake mushroom) mycelium (hyphae) extract which is prepared via the same steps as instantly claimed, as well as pharmaceutical, drink, oral (food) formulations thereof, and a method of treating viral diseases such Hepatitis B, as well as HIV therewith (see, e.g., paragraphs [0009], [0010], [0015] - [0042] and claims).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a therapeutic anti-viral *Lentinus edodes* (shiitake) mycelium extract via the instantly claimed steps, including formulating such therapeutic extracts into conventional pharmaceutical, drink, and/or oral (e.g., food) preparations, as well as to treat viral infections therewith (such as those instantly claimed, including Hepatitis B and other viral infections), based upon the beneficial teachings provided by the cited reference with respect to such anti-viral activity. Please note that the other claim limitations (e.g., that the extract has a particular cell functional activity and/or that it comprises approximate ranges of various ingredients therein) would be intrinsic to the *Lentinus edodes* mycelium extract taught by US '330. The result-effective adjustment in conventional working conditions/parameters (e.g., providing such an extract within one or more conventional pharmaceutical formulations such as those instantly claimed and/or treating a particular type of viral infection - especially given that no demonstrated working examples have been provided within the instant disclosure with respect to treating a particular type of viral infection, including those instantly claimed) is deemed

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merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the cited reference, especially in the absence of evidence to the contrary.

Claims 26-29 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagaoka (JP 61103816 - JPAB and DWPI Abstracts).

The cited reference teaches a *Lentinus edodes* (also known as shiitake mushroom) mycelium extract having antibacterial (antibiotic) activity (thus, useful for treating bacterial infections), which is prepared via the same (or essential the same) steps as instantly claimed, as well as pharmaceutical (e.g., cream) formulation thereof (see, e.g., JPAP and DWPI Abstracts).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a therapeutic anti-viral *Lentinus edodes* (shiitake) mycelium extract via the instantly claimed steps, including formulating such therapeutic extracts into conventional pharmaceutical, drink, and/or oral (e.g., food) preparations, as well as to treat bacterial infections (such as those instantly claimed), based upon the beneficial teachings provided by the cited Nagaoka reference with respect to such anti-bacterial activity. Please note that the other claim limitations (e.g., that the extract has a particular cell functional activity and/or that it comprises approximate ranges of various ingredients therein) would be intrinsic to the *Lentinus edodes* mycelium extract taught by JP 61103816. The result-effective adjustment in conventional working conditions/parameters (e.g., providing such an extract within one or more conventional pharmaceutical formulations such as those instantly claimed and/or treating a

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particular type of bacterial infection - especially given that no demonstrated working examples have been provided within the instant disclosure with respect to treating a particular type of bacterial infection, including those instantly claimed) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited references as a guide.

Thus, the invention as a whole is *prima facie* obvious over the cited reference, especially in the absence of evidence to the contrary.

Applicants' arguments (presented within the response filed 28 July 2005) as they pertain to the above art rejections have been carefully considered but are not deemed to be persuasive of error in the rejections. Applicants argue that the Nagaoka US '615 reference only makes the passing reference that the "cell wall lysis product-containing liquid (ii) contains beta glucan in high concentration shows excellent antitumor effects" in the Abstract, and that the inventors of the '615 patent did not actually test any anti-tumor activity of their extract including one having the instantly claimed functional cell activity effect. However, US '615 also clearly discloses at column 1, lines 30-44, that their *Lentinus edodes* (shiitake) mycelium extract is effective as an anti-tumor agent including its inhibitory effect against sarcomas and malignant tumors. With respect to demonstrating the anti-tumor effect of the extract taught by US '615, it should be noted that the instant Applicants also did not provide any working examples demonstrating such *in vivo* anti-tumor activity. In addition, as discussed above, the functional cell activity effect instantly claimed would be intrinsic to the *Lentinus edodes* mycelium extract taught by US '615.

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Applicants further argue that the present invention specifically recites that the extract of *Lentinus edodes* mycelium used in the claimed method is made by digesting the *Lentinus edodes* mycelium with one or more enzymes selected from cellulase, protease, and glucosidase (see, e.g., col 6, lines 55-44 of US '615), whereas the preparation method of US '615 on the other hand uses "Fanselase" which is a cell wall lytic enzyme. However, US '615 expressly discloses that one or more enzymes may be used in preparing their *Lentinus edodes* mycelium extract including cellulase, protease, and glucanase, making this instantly claimed step limitation (within the recited product-by-process steps of the instant method claims) clearly obvious to one of ordinary skill in the art.

Applicants additionally argue that JP '816 does not teach antibacterial use of their *Lentinus edodes* (shiitake) mycelium extract. However, as discussed above, the JPAB and DWPI English Abstracts of this document expressly teach that their *Lentinus edodes* mycelium extract has antibacterial (antibiotic) activity (see JPAB Abstract - in the paragraph beginning with "PURPOSE", and the DWPI Abstract - in the paragraph beginning with 'ADVANTAGES').

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Christopher R. Tate', with a stylized, looping initial 'C'.

Christopher R. Tate
Primary Examiner
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